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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,105	09/10/2004	Takayuki Fujii	Q83547	2105

23373 7590 07/28/2006

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/507,105	**Applicant(s)** FUJII, TAKAYUKI	
	Examiner Paul C. Martin	**Art Unit** 1655	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 July 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: 11-25.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached continuation sheets.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 04/26/06
13. ☐ Other: _____.

PATRICIA LEITH
PRIMARY EXAMINER

ADDENDUM TO THE ADVISORY ACTION

The Applicant's explanation of the terms "exhibiting" in the recitation " a concentration exhibiting the lactate dehydrogenase activity" in regards to the rejection under 35 U.S.C. § 112 in the reply filed 07/10/06 have been considered and are found persuasive.

The applicant argues that the reaction formulas are distinct between the instant invention and that of Misapply *et al.*, and through the use of the LD inhibitor exhibiting the LD activity which does not affect the measurement of the ALT activity, and that there are advantageous and remarkable effects to using the claimed inhibitor concentrations such as an increased blank reaction, more accurate measurements of ALT activity, and LD stabilization.

The Applicant's arguments are not found persuasive because though the reaction pathways are not exactly the same, the reaction steps and components of Misapply *et al.* as taught meet the conditions for obviousness under 35 U.S.C. 103 (a) over Misapply *et al.* because one of ordinary skill in the art would have recognized that although written reaction formulas are not identical, the components of the reactions are the same (i.e., the example in Column 6, Lines 38-68 and Column 7, Lines 1-35, wherein a blood sample is contacted with L-alanine, 2-oxoglutaric acid, lactate dehydrogenase, NAD, oxalic and oxamic acid), therefore the reactions of the Applicants formula will inherently occur as well.

Misapply *et al.* certainly utilizes an LD inhibitor which "exhibits the LD activity which does not affect measurement of the ALT activity", because giving the term its broadest, reasonable interpretation, the oxamic and oxalic acid inhibitors are used in concentrations which exhibit an LD activity (none) which does not affect the measurement of ALT.

The Applicant's arguments of advantageous and remarkable effects to using the claimed inhibitor concentrations such as an increased blank reaction, more accurate measurements of ALT activity, and LD stabilization are unfounded as nowhere in the instant disclosure or working examples is disclosed a comparison of other concentrations of the inhibitors such that a clear advantage over say, the concentrations used by Misapply *et al.* can be discerned.

Further it is noted, that Misapply *et al.* teaches the use of enzyme (GLDH) stabilizer (Column 5, Lines 51 and 52) and that the "improved method eliminates color development due to non-specific reactions of Glutamate dehydrogenase (GLDH) in the presence of beta-nicotinamide adenine dinucleotide with endogenous amino acids in the biological fluid, while eliminating the reaction of both added and endogenous lactate dehydrogenase, thereby materially increasing the accuracy of the determination." In light of these teachings, the Applicant has not demonstrated that the claimed invention is novel and distinct from that of the prior art and therefore all of the rejections under 35 U.S.C. 102 (b) and 103(a) of the previous action are maintained.